इंटरनेट मानक

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IS 8313 (1977): Cannula, Flexible, Karman Type [MHD 3: Obstetric and Gynaecological Instruments and Appliances]

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“Knowledge is such a treasure which cannot be stolen”

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Indian Standard

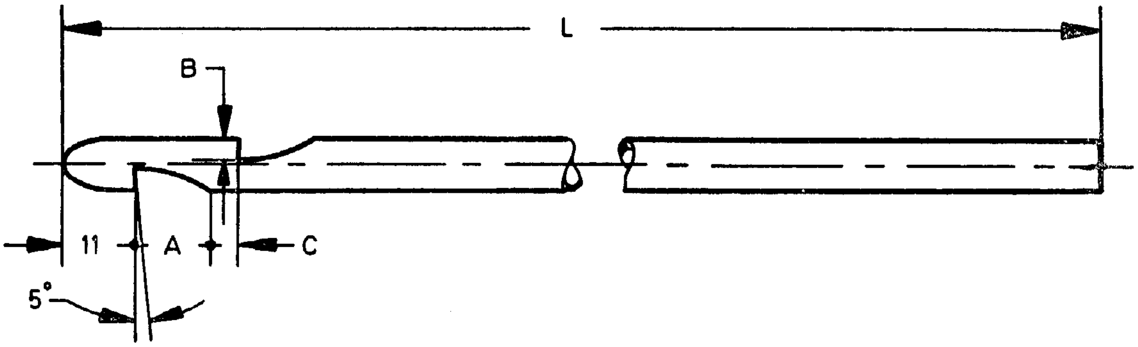
(Reaffirmed 1997)

SPECIFICATION FOR CANNULA, FLEXIBLE, KARMAN TYPE

Obstetric and Gynaecological Instruments & Appliances Sectional Committee, CPDC 25 [Ref : Doc : CPDC 25 (1001)]

1. Scope — Dimensional and other requirements for disposable Karman Type flexible cannula for menstrual regulation and medical termination of early pregnancy.

2. Shape and Dimensions — As shown in Fig. 1.



Size	OD	ID	A	B	C	L
1	4	3·0	6·0	1·80	2·0	200
2	5	3·5	7·5	2·25	2·5	200
3	6	4·5	9·0	2·70	3·0	200
4	8	6·5	12·0	3·60	4·0	230
5	10	8·0	15·0	4·50	5·0	230
6	12	10·0	18·0	5·40	6·0	230

All dimensions in millimetres.

FIG. 1 CANNULA, FLEXIBLE, KARMAN TYPE

2.1 A deviation of ±2·5 percent shall be allowed on all dimensions.

3. Material — Non toxic low density polyethylene of Grade G of IS : 3395-1965 'Specification for low density polyethylene materials for moulding and extrusion'.

4. Workmanship and Finish

4.1 All surfaces of cannula shall be free from pits, dents, burrs, scales and other defects.

4.2 V-shaped notches at the working end of the cannula shall be well formed.

4.3 The closed tip of the cannula shall be rounded and hemispherical.

4.4 The open end of the cannulae shall be provided with suitable sleeves, where, necessary to give leak-proof fitting with the corresponding component.

5. Tests

5.1 The cannula in their ready for use state shall be compatible with human tissue without causing toxic, allergic or fibrous reaction.

5.2 *Test for Toxicity*

5.2.1 Fill a 150 mm length of cannula, by plugging open ends, with sterile pyrogen-free isotonic saline solution containing 9 g of sodium chloride per litre and immerse the filled set completely in water. Heat the water and maintain at not less than 85°C for 1 hour. Drain the contents of the cannula. Inject intravenously 0·5 ml of the solution so prepared into each of five healthy mice weighing 20 ± 3 g. At the end of 4, 24 and 48 hours examine the animals for discernible symptoms of toxicity. If any of the animals show gross signs of toxicity or die, repeat the test with five unused mice weighing 20 ± 3 g each. The test shall be deemed to be satisfied if all the animals survive for 48 hours.

[redacted] Gr 1

Adopted 13 January 1977	© April 1977, ISI	Price Rs 5·00

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NEW DELHI 110002

5.2.2 Heavily inoculate a blood-agar plate over the entire surface with a young broth culture of streptococcus pyrogens. The blood-agar plate shall consist of nutrient agar containing 10 percent of horse blood in a petri dish. Select 5 mm length of representative sample of the cannula. Wash the cannula sample in distilled water, then sterilize them by autoclaving in distilled water for 30 minutes at 120°C. Rinse twice in sterile distilled water and dry. Place the samples on the blood-agar surface applying slight pressure observing the usual asceptic precautions, with a minimum distance of 20 mm between each item. Incubate the whole thing at 37°C for 24 to 48 hours. In the absence of inhibitory substances, the growth of streptococcus pyrogens right to the edge of the sample, is evidenced by haemolysis of the red blood cells. In the presence of inhibitory substances, there is a ring of unhaemolysed block without bacterial growth around the sample.

5.3 The cannula, though flexible, shall have sufficient rigidity not to get flattened under a vacuum of 700 mmHg. When not in use, the cannula shall reasonably maintain their circular cross section.

6. Instructions

6.1 The cannula shall be supplied with instructions giving the following:

a) Disposable, supplied sterilized and ready for use; and

b) Instructions for use : To be connected to a suction device, capable of giving vacuum up to 86·4kN/m² (approximately 650 mmHg) for MR and 93·1kN/m² (approximately 700 mmHg) for MTP up to an altitude of 200 m above sea level.

7. Marking

7.1 Cannula shall be marked with the manufacturer's name, initials or recognized trade-mark and size number in mm.

7.2 *ISI Certification Marking* — Details available with the Indian Standards Institution.

8. Packing — The cannula shall be packed as agreed to between the purchaser and the supplier. The packing shall be such as to avoid deformation of any cannula.

EXPLANATORY NOTE

This instrument is for use by trained surgeon only. It is expected that the performing surgeon is well versed with the procedure for medical termination of early pregnancy. The total responsibility for any procedure using this instrument is that of the surgeon.

Printed at Delhi Printers, Delhi. India